

---REMARKS---

Claims 1, 2, 4, 7, 8, 10, 14-16, 19, 20, 23, 26, 28-30, 35-37, 39, 40, 44-47, 50, 51, 53, & 56 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al (US 7,021,940) in view of Gordon et al (US 7,021,940). Claims 1, 19, 29, 36, and 39 are the independent claims of the group.

The Applicant respectfully submits that Morris in view of Gordon does not teach every element of the Claims 1, 19, 29, 36, and 39. This is the first opportunity for the Applicant to respond to rejections based on Gordon.

Regarding claims 1, 29, and 39 neither Morris nor Gordon teach, individually or in combination, of an apparatus for simulating human blood pressure cycles where an electronic control unit controls pressure amplitude oscillations of the pressurized fluid inside a pressure vessel between simulated human systolic and diastolic blood pressure levels at a frequency equivalent to a human cardiac pulse rate; a pressure sensor in contact with the pressurized fluid electronically senses pressure levels within the pressure vessel and provides pressure data feedback to the electronic control unit and where a human senses, through tactile contact with the pressure vessel, the simulated diastolic and systolic blood pressure levels within the pressure vessel. The Examiner states that Morris does not teach "where the electronic control unit controls pressure amplitude oscillations of the pressurized fluid inside the pressure vessel between simulated human systolic and diastolic blood pressure levels [Claim 1] and where the pressure sensor is in *pneumatic* contact with pressurized fluid [Claim 1]." However, the Examiner states that it would have been obvious to use the teaching of Gordon's electrical contacts in contact with mercury in a manometer connected to a sphygmomanometer-type device to combine with Morris to achieve the Applicant's pressure sensor in contact with the fluid in the tactile interface vessel. The Applicant disagrees. The Applicant submits that a mercury

manometer can in no way respond to accurate measurements of pressure at the frequency of 60-120 cycles per minute (1 to 2 cycles per second) corresponding to a human pulse rate (Claims 1 and 39) (or a simulated human blood pressure cycle, Claim 29) so this suggested combination has no chance of success to function like the Applicant's claimed device. Gordon's mercury manometer teachings are clearly away from dynamic blood pressure simulation which is present in Applicant's claims since it is well known that manometers cannot accurately respond to rapidly changing, time varying pressures. Further, the presence of metal contacts within a mercury manometer column does not teach that a pressure sensor is in contact with the pressurized fluid in the tactile pressure vessel experiencing diastolic and systolic pressure swings since metal contacts are not pressure sensors but rather the metal contacts taught by Gordon are simple electrical conductors (element 64 in Gordon). Metal contacts inside a mercury manometer tube would serve no useful purpose in an oscillating pressure field as experienced in the Applicant's pressure vessel since the manometer column would be useless to measure these time varying pressure levels.

Further, the combination of Morris and Gordon does not teach an electronic control unit that controls pressure amplitude oscillations of the pressurized fluid inside the pressure vessel between simulated human systolic and diastolic blood pressure levels at a frequency equivalent to a human cardiac pulse rate. The Examiner admits that Morris fails to teach this in the Final Rejection (mailed 9/26/07). However, the Examiner states that it would have been obvious to use Morris' electronic control unit to control pressure amplitude oscillations in the fashion of Gordon to meet claims 1, 29, and 39. Again, the Applicant submits that Gordon's mercury manometer could not possibly respond quickly enough to control diastolic and systolic pressure levels at a human pulse rate so this combination could not possibly meet with success as the Examiner suggests. Further, Gordon does not teach of any pressure level control by his system,

but rather he simply teaches the turning on and off of audio sounds in a stethoscope (column 8, lines 51-54). Also, Gordon does not teach of a system having oscillating fluid pressure levels in simulated blood vessels, so a skilled artisan would not have any motivation to even look to Gordon to control oscillating pressure levels in a pressure vessel having a tactile interface as in the Applicant's claims.

Even further, the Applicant submits that for another reason it would be impossible to combine the systems of Gordon and Morris as suggested by the Examiner to control pressure amplitude oscillations of the pressurized fluid inside the pressurized vessel between simulated human systolic and diastolic blood pressure levels. Both Morris and Gordon teach of conventional, manually operated sphygmomanometer bulbs and cuffs which cannot possibly accurately inflate and deflate a blood pressure cuff 60-120 times per minute to keep pace with a human pulse rate to control systolic and diastolic pressures. It is well known that a manual inflation pump (bulb) of a commonly used blood pressure measurement device cannot be operated to produce accurate diastolic and systolic pressures in a standard cuff even approaching a human pulse rate. Such manual pumps (inflation bulbs) have check valves to provide unidirectional pumping action of air into a cuff and a bleed valve to deflate the cuff. Therefore, the Applicant submits that this is another reason why the Examiner's suggested combination of the teachings of Morris and Gordon would not possibly meet with success in satisfying the Applicant's claims 1, 29, and 39 and thus the rejections are improper.

The Applicant respectfully submits the Examiner has misinterpreted that the electronic control unit of Morris is understood to sense the systolic and diastolic pressures of a blood vessel in a body as stated on page 4 of the Final Rejection (mailed 9/26/07) in rejecting Claims 1, 29, and 39. The Applicant respectfully submits that this is simply not how Morris' device operates. The pressure sensor in Morris simply measures the pressure inside a blood pressure cuff 21 and

compares the pressure reading from its pressure sensor via an electronic comparator 23 to an input blood pressure setting 24 whereby when the slowly increasing pressure level in the cuff 21 being manually inflated exceeds the comparator level, the solenoid valve 403 is maintained closed and pulsations cease. The solenoid valve 403 in Morris simply drives the on-off pulsing of simulated blood in a simulated brachial vessel to simulate the presence of a pulse without regard for controlling or adjusting specific systolic and diastolic pressure levels in the brachial vessel 401 (to which the Examiner has admitted on page 3, lines 10-12 of the Final Rejection). Column 7, lines 55-67 and column 8, lines 1-3 of Morris state "*Whilst the trainer is preparing to take the blood pressure by wrapping the inflatable cuff 21 over the arm above the brachial simulating vessel 401 and subsequently inflating the cuff 21, the processor 8 will generate a signal to close the third solenoid valve 403 once the comparator 23 determines that the cuff pressure exceeds the input blood pressure 24. This will have the effect of cutting off the flow to the brachial vessel simulating bladder 401 in much the same manner as blood flow will be cut off from a real brachial vessel when the inflatable cuff pressure exceeds the systolic blood pressure. To take the systolic blood pressure, the trainee uses a stethoscope in the usual manner to detect the commencement of pulsating flow of blood as the cuff pressure is reduced back down to below the input blood pressure, being the point at which the processor 8 again resumes the cyclic opening and closing of the third solenoid valve 403*". It is noted that Morris teaches that when the comparator 23 stops the solenoid valve 403 from pulsing ("closes it" as he calls it), he states that this has the "same effect" as cutting off the flow to the brachial vessel 401 "in much the same manner" as blood flow will be cut off from a real brachial vessel when the inflatable cuff pressure exceeds the systolic blood pressure. The "same effect" here is to stop the blood flow in the vessel, but Morris implies that the physics are much different but have the "same effect." In a "real brachial vessel" in a human, the systolic pressure in the cuff occludes flow in the vessel

but doesn't stop the pulsation source, ie the human heart. This is clearly not the case in Morris' apparatus since the brachial vessel is not occluded (and therefore the pressure is not measured) but rather the pulsation source is stopped when the pressure in the cuff exceeds the input blood pressure setting by the user.

It is important to note that Morris does not teach anything about measuring a diastolic blood pressure. Further, it is noted that the word *diastolic* never appears in Morris' disclosure and the word *systolic* only appears twice and those times are in the passage cited above. Morris does not teach simulation of human level systolic or diastolic pressures in his system since his system operates as a trainer by simply using a comparator circuit to start and stop the cycling of solenoid valve 403 thus, never needing to accurately simulate systolic or diastolic pressures in the simulated blood vessels which experience the pulsating flow. Morris' training system only needs to start the pulsations again though the comparator 23 when the pressure in cuff 21 is decreased below the blood pressure setting by the trainee such that the trainee can start to hear the pulsations in the stethoscope. It is only the blood pressure cuff 21 that actually may experience an accurate, but steady systolic blood pressure level in the system of Morris which is entirely independent of any pressure existing in the brachial vessel 401. It is emphasized that the cuff 21 in Morris need not even be connected to the manikin at all to have the same effect on stopping the solenoid valve 403 from pulsing as the cuff pressure increases to equal the comparator setting, thus there is no measurement of simulated blood pressure levels in vessels experiencing pulsations taught by Morris. This is a most important point the Applicant most respectfully submits that the Examiner has overlooked in the operation of Morris' device. Stated another way, the cuff 21 does not occlude the simulated brachial vessel 4001 to stop the simulated blood pulsations therein but rather only the pressure level in the cuff 21 compared to a comparator level setting that starts or stops the solenoid valve 403 pulsations. Therefore, there is

no control of the level of pulsations in the simulated vessels of Morris' device but rather there simply are pulsations or there are not pulsations (a binary system). The steady or near-steady pressure levels in the blood pressure cuff 21 and the pulsating pressures in the simulated brachial blood vessel are not the same in Morris' apparatus even as the pulsations in the brachial vessel 401 are stopped by the comparator circuit.

Finally, the column 7, lines 28-34 of Morris state that *"The present inventors have found that a pulse rate can be most realistically simulated where the control signal provides a constant solenoid valve 403, 503 opening time, with the solenoid valve 403, 503 closing time varying to account for variations in pulse rate. That is, for a slower pulse rate the solenoid valve 403, 503 closing time will be increased whilst maintaining a constant solenoid valve opening time."* The Applicant points to this teaching as further evidence that there is no control over the pressure levels in the simulated blood vessels in Morris' apparatus. With a fixed opening time for the solenoid valve 403 which drives the pulsations in the simulated blood vessels, there can be no control of the pressure pulse amplitude. Morris only teaches about adjusting the pulse rate and not the amplitude of the pulse.

Neither cited reference teaches, alone or in combination, of an electronic unit to control pressure amplitudes oscillations and of a pressure sensor in contact with the fluid inside the pressure vessel to provide pressure data feedback to the electronic control unit to actively control the pressure levels in the vessel. Even further, the Examiner states that a "pressure sensor electronically senses pressure levels within the pressure vessel (via a comparator circuit)" (page 3 of 9/26/07 Final Rejection lines 6-7) but he fails to point out that this pressure vessel (cuff) 21 cited in Morris is a blood pressure cuff which is not experiencing diastolic and systolic pressure oscillations at human pulse rates; however these rapid pressure oscillations are features of Claims 1, 29, and 39. Neither Morris nor Gordon alone or in combination teach of diastolic and

systolic pressure level control in a pressure vessel experiencing pressure oscillations between systolic and diastolic pressure levels at a human pulse rate.

Taking the Applicant's argument yet another step further, the Applicant submits that even if the cuff 21 of Morris did somehow function to measure the pressure within the brachial vessel 401, it would be impossible to measure the systolic and diastolic pressures (if they existed) in the brachial vessel 401 at a human pulse rate since the pressure in the cuff 21 could not possibly be manually increased and decreased accurately 60-120 times per minute to keep up with accurate systolic and diastolic pressure levels at a human pulse rate. Morris clearly teaches that the cuff 21 and manual pump having a pressure gauge as commonly used for the measurement of blood pressure (column 7, lines 46-49) are used in his system. It is well known that a manual inflation pump (bulb) of a commonly used blood pressure measurement device cannot be operated to produce accurate diastolic and systolic pressures in a standard cuff even approaching a human pulse rate. Such manual pumps (inflation bulbs) have check valves to provide unidirectional pumping action of air into a cuff and a bleed valve to deflate the cuff. Therefore, the Applicant submits that the teaching of Morris is very different than the Applicant's claims of having a pressure sensor in contact with the fluid inside a pressure vessel whereby the pressure sensor measures the pressure levels inside the vessel and provides data feedback to an electronic control unit to control the pressure amplitude oscillations within the vessel between simulated systolic and diastolic blood pressure levels at a frequency equivalent to a human cardiac pulse rate.

Still further, the Examiner's suggested combination of Gordon's teachings with Morris would render Morris' device unsuitable for its intended use since the suggested mercury manometer pressure control could not possibly permit Morris' pulsations at the rate he intended due to frequency response limitations of the manometer.

The Applicant submits that the Examiner has not proven a case of prima facie obviousness in combining the teachings of Morris with Gordon in an attempt to meet the Applicant's claims 1, 29, and 39 since the cited references do not teach every elements of the claims. Nor would it be technically possible to combine the references as suggested by the Examiner to meet the Applicant's claims.

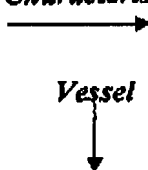
The Applicant also submits that neither Morris nor Gordon teaches, alone or in combination, of a pressure vessel with a tactile interface where a human senses, through tactile contact with the pressure vessel, the simulated diastolic and systolic blood pressure levels within the pressure vessel. Morris simply teaches that the simulated pressure vessels 401 and 501 "when felt by manual touch has the realistic feel of a regular pulse rate" (column 7, lines 16-18). Neither Morris nor Gordon teach that by tactile contact with a pressure vessel can one sense the magnitude of simulated diastolic and systolic blood pressure levels within the vessel which is very much different than manually feeling a vessel within a simulated body part for the mere presence of pulse. Therefore, not every element of Claims 1, 29, and 39 are taught by the reference cited by the Examiner and thus, the rejections are improper.

In order to facilitate sorting out some of the various characteristics of the Applicant's claimed elements in Claims 1, 29, and 39 from the cited references of Morris and Gordon, the Applicant has constructed Table 1. While not at all intended to be an exhaustive summary description, Table 1 summarizes some of the arguments presented by the Applicant why not every element of Claims 1, 29, and 39 is taught by Morris in view of Gordon as suggested by the Examiner.

The Applicant respectfully submits that the rejections of Claims 1, 29, and 39 are improper since the Examiner has failed to show that all of the elements of the Applicant's claims are taught by the cited references of Morris in view of Gordon. The Examiner has also failed to

prove that Claims 1, 29, and 39 are obvious in view of the cited references due to there being no chance of success in meeting the Applicant's claims if the cited references were combined as the Examiner suggests and due to a teaching away of combining the reference in the manner suggested by the Examiner. The Applicant submits that the Examiner has not properly shown Claims 1, 29, and 39 to be obvious under 35 U.S.C 103(a), and the Applicant therefore requests that the rejections be withdrawn and Claims 1, 29, and 39 be allowed.

**Table 1: Comparison of Characteristics of Pressure Vessels Cited in References and in Applicant's Claims 1, 29, and 39**

| <b>Characteristic</b><br> | <b>Pressure pulses in vessel at human pulse rate?</b>                                                                                                           | <b>Oscillating internal pressure at controlled systolic and diastolic levels to simulate human blood pressure cycles?</b>                                                                                                   | <b>Oscillating pressure levels in vessel <u>measured</u> at human pulse rate?</b>                                                                                                                                       | <b>Human senses through tactile contact with vessel the diastolic and systolic pressure levels at human pulse rates?</b>                                                                                                |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b><i>Morris Cuff 21</i></b>                                                                               | No<br>Standard sphygmomanometer bulb cannot produce required pressures as function of time due to unidirectional flow in such bulbs serving as manual pumps     | No<br>Standard sphygmomanometer bulb cannot produce required pressures as function of time due to unidirectional flow in such bulbs serving as manual pumps                                                                 | No<br>Standard sphygmomanometer bulb cannot produce required pressures as function of time due to unidirectional flow in such bulbs therefore no oscillating pressure at human blood pressure pulse rate can be present | No<br>Standard sphygmomanometer bulb cannot produce required pressures as function of time due to unidirectional flow in such bulbs therefore no oscillating pressure at human blood pressure pulse rate can be present |
| <b><i>Morris Simulated Brachial Blood Vessel 401</i></b>                                                   | Yes<br>Solenoid valve 403 opens and closes in a binary fashion to create a pulse in simulated blood vessels; systolic and diastolic pressure levels not taught  | No<br>No pressure feedback data control of pressure levels, just solenoid valve open or closed; no teaching of accurate diastolic and systolic pressure levels                                                              | No<br>There is no mechanism taught to measure the pressure in the simulated brachial vessel 401; cuff 21 does not measure the pressure in brachial vessel 401                                                           | No<br>Human diastolic and systolic pressure levels in simulated blood vessel are not taught and vessels buried in a simulated arm provide tactile feeling of pulse presence only                                        |
| <b><i>Gordon Cuff 69</i></b>                                                                               | No<br>Conventional sphygmomanometer bulb cannot produce required pressures as function of time due to unidirectional flow in such bulbs serving as manual pumps | No<br>Conventional sphygmomanometer bulb cannot produce required pressures as function of time due to unidirectional flow in such bulbs and mercury manometer cannot respond to human pulse rate changes in pressure levels | No<br>Mercury manometer cannot respond to dynamic pressure changes and conventional sphygmomanometer bulb cannot produce required pressures as function of time due to unidirectional flow in such bulbs                | No<br>Conventional sphygmomanometer bulb cannot produce required pressures as function of time due to unidirectional flow in such bulbs therefore no oscillating pressure at human blood pressure cycles can be present |
| <b><i>Applicant's Pressure Vessel 120</i></b>                                                              | Yes<br>Accurate human systolic pressure and diastolic pressure levels provided at human pulse rate                                                              | Yes<br>Accurate human systolic and diastolic pressure levels provided at human pulse rate                                                                                                                                   | Yes<br>Pressure sensor 130 in contact with vessel fluid measures pressure levels in vessel and provides data feedback to electronic control unit 140                                                                    | Yes<br>Pressure vessel with tactile interface can be free of being buried such as in simulated human body parts                                                                                                         |

Claims 19 and 36

Regarding Claims 19 and 36, Morris in view of Gordon fails to teach every element of the claims and explicitly teaches away from the cited combination of Morris and Gordon. It is noted that the Examiner appears to cite elements where he states what Morris teaches based on the previous amendment and not the amendment to which this Final Rejection pertains (see page 6 of 9/26/07 Final Rejection lines 6-10 and compare to the struck elements in Claim 1 in Amendment G). The Examiner states that Morris fails to teach of a device to produce the periodic pressure amplitude cycles within the pressure vessel, the cycles comprising at least one abnormal human blood pressure amplitude cycle (lines 17-19 of page 6 of the Final Rejection). The Examiner also states that Morris fails to teach where an electronic switch toggles between simulating the normal and abnormal blood pressure amplitude cycles (lines 7-8 of page 7 of the Final Rejection). In both cases the Examiner goes on to allege that Gordon's teachings combined with Morris meet claims 19 & 36. The Applicant respectfully submits that the Examiner is incorrect in each case.

As mentioned above, the teaching of Gordon does not control any pressure level but merely turns on and off audio sounds in a stethoscope according to the 15 disease combinations of Gordon cited by the Examiner. Neither does Morris teach control of systolic and diastolic pressure levels as mentioned above. Even if Gordon's teaching was inventively employed to attempt to control the pressure levels in the pressure vessel in Morris, the thirty contacts in a mercury manometer tube of Gordon cited by the Examiner could not possibly be used to control pressure levels oscillating between simulated diastolic and systolic pressures at human pulse rates due to the very limited frequency response of a mercury manometer system (cannot possibly respond to 60 to 120 cycles per minute). Therefore, the Examiner's suggested combination of Gordon's manometer teachings with Morris' teachings could not possibly meet

with success in satisfying the Applicant's Claims 19 and 36. The Examiner's cited combination of Gordon's teachings with Morris teachings would also render Morris' device unsuitable for its intended use since the suggested mercury manometer pressure control could not possibly permit Morris' pulsations at the rate he intended due to frequency response limitations of the manometer. Therefore, the Applicant submits the rejections of Claims 19 and 36 are improper.

Additionally, the Applicant submits that neither Morris nor Gordon teach of a device or method to produce or maintain pressure amplitude oscillations of the pressurized fluid inside the pressurized vessel between simulated human systolic and diastolic blood pressure levels at human pulse rates as the Applicant recites in Claims 19 and 36. Both Morris and Gordon teach of conventional, manually operated sphygmomanometer bulbs and cuffs (where only the cuffs are connected to a pressure measurement device) which cannot possibly accurately inflate and deflate a blood pressure cuff 60-120 times per minute to keep pace with a human pulse rate to control systolic and diastolic pressures. It is well known that a manual inflation pump (or even an automatic pump) of a commonly used blood pressure measurement device cannot be operated to produce accurate diastolic and systolic pressures in a standard cuff even approaching a human pulse rate. Such pumps have check valves to provide unidirectional pumping action of air into a cuff and a bleed valve to deflate the cuff. Therefore, the Applicant submits that the Examiner's cited references either alone or in combination do not teach every element or limitation of Claims 19 and 36; and therefore, the rejections under 35 U.S.C. 103(a) are improper.

The Applicant further submits that the Examiner has improperly referenced Gordon as teaching of the use of switches in combination with Morris to toggle between normal and abnormal blood pressure levels. Gordon is clearly on record as teaching away from the use of his disease selector switches (72 & 73) for controlling anything once his system has started. See column 8, lines 9-13 of Gordon where it states that once the system is started, changes in

switches 72 & 73 have no effect on the system since the data on output lines 76 is held steady even if switches 72 & 73 are changed. Therefore, Gordon explicitly teaches away from how the Examiner has combined Morris and Gordon in an attempt to meet claims 19 & 36 where these claims pertain to toggling between normal and abnormal pressure amplitude cycles using an electronic switch. Therefore, the Applicant submits that the Examiner has improperly rejected Claims 19 & 36 under 35 U.S.C. 103(a) since there is a clear teaching away from combining the cited references in the manner suggested by the Examiner.

Even further, the Applicant submits that the Examiner has improperly compared the use of pneumothroax input switch 17 in Morris to an electronic switch in the Applicant's Claims 19 and 36 to toggle between normal and abnormal blood pressure levels. First, one having ordinary skill in the art would not be motivated to look to Morris' teaching of a pneumothorax condition for relevancy to an abnormal blood pressure condition since these are vastly different health conditions, one being a cardiac function and one being a pulmonary function. Second, the Applicant's electronic switch selects between two states, normal and abnormal human blood pressure simulations. The pneumothorax input switch 17 of Morris is not a switch selecting between two states consisting of normal and abnormal lung function but rather a switch that is cyclically activated to select between the operation of both simulated lungs, the operation of only the first lung, and the operation of only the second lung (column, 5 lines 58-67 and column 6, lines 1-3).

The Applicant respectfully submits that the Examiner has not properly shown where each element of Claims 19 and 36 are taught by Morris in view of Gordon. The Applicant has traversed the Examiner's rejections by citing passages in Gordon which specifically teach away from the Examiner's suggested combination of the teachings of Morris and Gordon to meet the Applicant's claims. The Applicant has further shown where the combination of Morris and

Gordon as suggested by the Examiner would render Morris' device unsuitable for its intended purpose. The Applicant has shown how the combination of the teachings Morris and Gordon as suggested by the Examiner could not meet the Applicant's Claims 19 and 36. The Applicant has shown how the pneumothorax condition of Morris and the abnormal blood pressure condition of the Applicant are not similar. For at least these reasons the Applicant submits that the rejections based on 35 U.S.C 103(a) are improper and requests that the rejections of Claim 19 and 36 be withdrawn and the claims allowed.

#### Claims 42 and 57

Claims 42 and 57 are independent claims standing rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin (US 4,773,865) in view of Morris and further in view of Rosendahl (US 6,606,907). The Applicant notes that this is the first opportunity to respond to rejections based on Rosendahl. The Applicant submits that these rejections are improper as follows.

It is first recognized that rejecting Claims 42 and 57 on the bottom of page 11 and the top half of page 12 of the 9/26/07 Final Rejection, the Examiner appears to be referring to the claim elements of the previously amended Claims 42 and 57 and states that Baldwin teaches of a second elastomeric bulb (9/26/07 Final Rejection page 12, lines 2 and 3). However, it is clearly stated by the Examiner in the first sentence of section 25 on page 12 of the 9/26/07 Final Rejection that "What Baldwin and Morris further fail to explicitly teach is where the second bulb is a bulb (Applicant's emphasis) rather than being a tube such that the pressure-induced forces are amplified with the bulbs compared to within the conduit of smaller diameter than either the first or second bulb". The Examiner uses non-persuasive interpretations of Rosendahl to meet Claims 42 and 57. The Examiner states starting on the bottom of page 12 of the Final Rejection,

"However, Rosendahl teaches a measurement apparatus for tactile gripping by a human hand (hand, performing grasping, 1:27-28), which amplifies pressure induced forces (work and work rate, 1:44-47) using a bellows or bladder (2:1-11)." The Applicant most respectfully requests that the Examiner point to where Rosendahl teaches anything about force amplification in his disclosure. The Applicant submits rather that the Examiner is improperly using the hindsight teaching of the Applicant's own specification paragraph 0016 for teaching of force amplification principles rather than any teaching of Rosendahl to make the claim that Rosendahl teaches of force amplification. Only the Applicant's specification teaches of force amplification in a larger vessel compared to a smaller diameter tube. The Examiner's mere mention of some basic laws of engineering mechanics related to definitions of pressure and work is irrelevant and in no way provides evidence of force amplification within the bulb being directly squeezed by the user in Rosendahl's apparatus. The Examiner has not correctly identified any mechanical advantage used by Rosendahl required to cause force amplification within the bulb. The Applicant submits that even if Rosendahl's apparatus functioned like the Examiner suggests and somehow amplified the pressure induced forces applied to the input bulb of Rosendahl, that Rosendahl's apparatus would over-report the grip strength and related parameters input by the user, a situation not intended or taught by Rosendahl's in his disclosure. Therefore, the Applicant submits that Rosendahl does not teach of force amplification as the Examiner suggests and therefore the rejection of Claim 47 on this basis is improper.

An important point here is that the Examiner has failed to show the teaching of a second elastomeric bulb connected to a first elastomeric bulb through a bi-directional flow conduit of smaller diameter than either the first or second bulb where the user can physically sense the fluid pressure magnitudes internal to the second bulb by gripping the bulb with at least one hand (Claim 42). The Examiner has failed to show how the small diameter tubes taught by Baldwin

52, 52' & 54 are equivalent to larger diameter bulbs. In fact, the Examiner states that Baldwin's tube is not the same as a bulb. The Applicant submits that neither cited references Rosendahl nor Morris teach that a small diameter tube is the same as a larger diameter second bulb, the larger diameter second bulb being recited in Claim 42. All of the bulbs taught by the non-analogous art of Rosendahl are input first bulbs where a user must actively pump the bulb to provide input into the system to determine the user's grip strength and related parameters, not receive tactile output information from a second bulb as in the Applicant's claims. Therefore, Rosendahl does not teach where flow moves into an elastomeric bulb from a small diameter conduit where force amplification occurs in the bulb. The Examiner makes several reaching peripheral comments regarding Rosendahl, but never makes any proper technical argument that Rosendahl or Morris teach that a small diameter tube as taught by Baldwin is the same as a second bulb (output tactile bulb) in Claim 42 or that Rosendahl teaches of force amplification of flow from a small diameter tube to a larger bulb. Even further it is clear from the teachings of Baldwin that the simulated femoral blood vessels 52 and 52' and jugular blood vessel 54 cannot be gripped by at least one hand as is recited in Claim 42 since the vessels of Baldwin (52, 52' and 54) are buried below the surface of the mannequin in plastic packing material 44 by at least one diameter of the vessel (see Figs. 5 & 6). Baldwin seems to teach that only a simulated human pulse may be felt at best in these vessels where he states "In general, the pulse of the femoral artery 52' can be felt. The pressure in the exterior jugular vein 54 can be somewhat felt." (Column 4, lines 1-3). There is no teaching of the user being able to feel the magnitude or level of pressure within the vessels by gripping the vessels with at least one hand. In fact, vessels 52, 52', and 54 cannot be gripped by a human hand (as recited in Claim 42) due to their locations well below the surface of the mannequin plastic packing material 44. The Applicant submits that gripping the vessels directly and gripping the mannequin plastic packing material 44 containing a buried vessel are very

different phenomena resulting in very different feedback to the human performing the gripping since the packing material 44 would significantly attenuate and diffuse the pulsation amplitude within the buried vessel compared to a free vessel. Baldwin fails to teach of any normal or abnormal systolic or diastolic blood pressures being produced in the blood vessels 52, 52' and 54, but rather only teaches of pulsating simulated blood so the users of the mannequin can locate the vessels (Column 4, lines 24-28).

On page 19, line 19-21 of the Final Rejection, the Examiner states "Furthermore, it is well-known and obvious to any medical doctor or nurse that both pressure and pulse can be felt in an artery". While the Applicant admits that a pulse can be felt in an artery as the heart beats, the magnitude of pressure in the artery cannot be ascertained by palpation of the artery beneath the skin surrounded by other bodily tissues. The Applicant submits that pulsation amplitudes within a buried vessel would be significantly attenuated and diffused by surrounding media compared to a free vessel. The Applicant submits that if the level of pressure could be determined by simply feeling of an artery buried in other tissue as the Examiner appears to suggest, then blood pressure measuring equipment in doctor's offices would not be needed and used so ubiquitously as it currently is to determine if patients have normal or abnormal blood pressure levels. This is clearly not the case. Thus, the Applicant submits that any medical doctor or nurse knows that the magnitude of pressure cannot be determined by feeling of an artery buried beneath a surface and surrounded by other tissues. As further evidence, it is well known that hypertension is called the "silent killer" since it presents no physical symptoms including sensing the magnitude or level of one's own systolic and/or diastolic blood pressure levels by feeling one's own arteries within the body with the fingers, for example.

On page 20, lines 2-4 of the Final Rejection, the Examiner states "Because pressure is equal to force per unit area, and work is equal to the product of force in the direction of

displacement, the bulb of Rosendahl causes a force amplification of a user's grip". The Applicant submits that the Examiner's mere reciting of some basic laws of engineering mechanics is irrelevant and has no bearing on the presence of force amplification in Rosendahl's input bulb as the Examiner has stated. The Examiner has not correctly identified any mechanical advantage used by Rosendahl required to cause force amplification. Rosendahl only teaches of an input bulb, not any output vessel or bulb. Since Rosendahl's apparatus requires a user input to squeeze a bulb or bellows there is no amplification occurring in the input bulb. As a matter of fact, the actual grip strength is attenuated rather than amplified since the user must overcome the bulb wall recoil elasticity to squeeze the bulb. Also, the Applicant submits that if amplification of the grip somehow occurred as the Examiner suggests, then the apparatus of Rosendahl would over-report accurate grip strengths and related parameters which is not intended by the apparatus. Therefore, the Applicant submits that the Examiner has improperly interpreted the physics how Rosendahl's apparatus actually functions in that Rosendahl does not make use of force amplification.

On page 12 of the Final Rejection, in arguing Baldwin in view of Morris to meet Claim 42, the Examiner concludes that "Therefore it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have connected a visual pressure indicator, as in Morris, to the simulated femoral artery of Baldwin, in order to facilitate locating the simulated artery by pressure or pulse [Claim 42]". The Applicant submits that this conclusion by the Examiner has no bearing on the obviousness of Claim 42 since there is no element within that claim related to locating of a simulated artery by pressure or pulse. Even more, the Applicant submits that the addition of a pressure indicator to a simulated artery would not prove useful to assist in location of an artery by pressure or pulse. The Examiner has failed to indicate how that would be the case other than alleging it is so.

The Applicant submits for the above reasons that the Examiner has not shown that the cited references teach every element of Claim 42 nor has the claim been shown to be obvious through an attempted combination of the references. The Applicant submits that the rejection is improper under 35 U.S.C. 103(a) and requests that the rejection be withdrawn and Claim 42 be allowed.

Very similar arguments apply to Claim 57 where not all claim elements are taught by the cited references (Baldwin, Morris, and Rosendahl) or rendered obvious. The Examiner has failed to show that these references (Morris, Gordon or Rosendahl), even if combined, teach of an elastomeric bulb connected to a pressure generating element by a small diameter conduit resulting in force amplification in the bulb compared to the conduit whereby a device controls the pressure levels within the bulb to simulate normal and abnormal blood pressure levels within the bulb, the bulb being a tactile interface so the user can sense the blood pressure levels by tactile contact with the bulb. The Applicant most respectfully requests that the Examiner point to where Rosendahl teaches anything about force amplification in his disclosure. The Applicant submits rather that the Examiner is improperly using the teaching of the Applicant's own specification paragraph 0016 for teaching of force amplification principles rather than any teaching of Rosendahl to make the claim that Rosendahl teaches of force amplification.

An important point here is that the Examiner has failed to show the teaching of an elastomeric bulb connected to a conduit of smaller diameter than the bulb where the user can physically sense the fluid pressure levels internal to the bulb by tactile contact with the bulb. The Examiner has failed to show how the small diameter tubes taught by Baldwin 52, 52' & 54 are equivalent to larger diameter bulbs. In fact, he states that Baldwin's tube is not the same as a bulb. The Applicant submits that neither cited references Rosendahl or Morris teach that a small diameter tube is the same as a larger diameter bulb, the larger diameter bulb being recited in

Claim 57. All of the bulbs taught by the non-analogous art of Rosendahl are input first bulbs where a user must actively pump the bulb to provide input into the system to measure the user's grip strength and related parameters, not receive tactile output information from a second bulb as in the Applicant's claims. Therefore, Rosendahl does not teach where flow moves into an elastomeric bulb from a small diameter conduit where force amplification occurs in the bulb. The Examiner makes several reaching peripheral comments regarding Rosendahl, but never makes any proper technical argument that Rosendahl or Morris teach that a small diameter tube as taught by Baldwin is the same as a bulb (output tactile bulb) in Claim 57 or that Rosendahl teaches of force amplification of flow from a small tube to a larger bulb.

Even further it is clear from the teachings of Baldwin that the simulated femoral blood vessels 52 and 52' and jugular blood vessel 54 cannot be tactilely contacted by a human as is recited in Claim 57 since the vessels of Baldwin (52, 52' and 54) are buried below the surface of the mannequin plastic packing material 44 by at least one diameter of the vessel (see Figs. 5 & 6). Baldwin seems to teach that only a simulated human pulse may be felt at best in these vessels where he states "In general, the pulse of the femoral artery 52' can be felt. The pressure in the exterior jugular vein 54 can be somewhat felt." (Column 4, lines 1-3). There is no teaching of the user being able to feel the pressure level within the vessels by tactile contact with the vessels; the vessels are not even directly accessible for tactile contact. Baldwin fails to teach of any normal or abnormal systolic or diastolic blood pressures being produced in the blood vessels 52, 52' and 54, but rather only teaches of pulsating simulated blood so the users of the mannequin can locate the vessels (Column 4, lines 24-28).

On page 12 of the Final Rejection, the Examiner states that while Baldwin fails to teach of abnormal blood pressure levels within the bulb, Morris "teaches simulating cyclic normal and abnormal fluid flow conditions with various fluid carrying body cavities, such as blood flow

within a blood vessel (4:17-25). Therefore it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to simulate blood flow conditions, as taught by Morris, in the blood pressure simulator of Baldwin, for the purpose of providing a useful element in health care training, especially for emergency procedures [Claim 57]." The Applicant submits that this is not at all what this passage teaches. The passage (4:17-25) cited by the Examiner is *"The system described above can be used to simulate fluid flow conditions within various fluid carrying body cavities, including in particular respiratory air flow within a pair of lungs or blood flow within a blood vessel. The system may also be utilised to simulate other conditions such as fluid pressure acting on the skull of a patient. A series of systems as described can be utilised to simulate various conditions within various fluid carrying body cavities of a single manikin."* The Applicant submits that this cited passage in no way teaches of the presence of normal or abnormal blood pressure in the apparatus of Morris as claimed by the Examiner. In fact, the words "normal" or "abnormal" never appear in Morris' entire disclosure. The Applicant submits that the Examiner has presented no evidence on which to base his conclusion and respectfully requests that the Examiner point to where in this passage he believes the presence of normal and abnormal blood pressure in Morris to be explicitly taught. The Applicant has previously shown that Morris does not teach of the presence of controlled systolic and diastolic pressure levels and in fact teaches away from their presence by the physical limitations of his apparatus (fixed solenoid 403 open time, no pressure level control, etc.). The Applicant submits that the Examiner must consider the teaching of Morris as a whole, even parts which teach away from what the Examiner suggests to meet the Applicant's claim.

For the several above reasons, the Applicant submits that the Examiner has failed to show that a combination of the cited references of Baldwin, Morris, and Rosendahl teach every

element of Claim 57 nor do the references render the claim obvious under 35 U.S.C. 103(a). Therefore, the Applicant requests that the rejection be withdrawn and Claim 57 be allowed.

Regarding all dependent claims that stand rejected, for the sake of brevity in this Response After Final Rejection, the Applicant submits that all dependent Claims 2-4, 7-11, 13-13, 16, 20-23, 25-41, 43-47, 50, 51, 53, and 55-56 are allowable since all of the respective independent claims on which the dependent claim depend have been traversed and the dependent claims contain all of the limitations of their respective independent claims and any intervening claims. The Applicant therefore submits that for at least this reason that dependent Claims 2-4, 7-11, 13-13, 16, 20-23, 25-41, 43-47, 50, 51, 53, and 55-56 are in condition for allowance. The Applicant hereby requests that the rejections be withdrawn for Claims 2-4, 7-11, 13-13, 16, 20-23, 25-41, 43-47, 50, 51, 53, and 55-56 and the claims allowed.

#### Summary

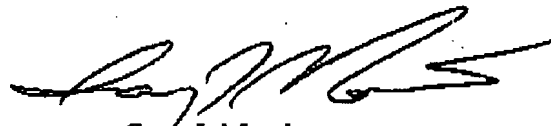
In responding to the Final Rejection mailed 9/26/07, the Applicant has made no amendments to the claims but has very carefully traversed each rejection to the independent claims presented by the Examiner. The Applicant believes that all of the independent claims are in condition for allowance. Since the dependent claims have all of the limitations of their respective independent claims and any intervening claims, the Applicant believes that the dependent claims are in condition for allowance.

The Applicant points out that the record shows at this late stage in the prosecution of this application (greater than four years of pendency and six office action responses from the Applicant including the present one), a total of six different prior art searches have been performed by multiple different Examiners assigned to this application. In the spirit of the

principle of compact patent prosecution encouraged by the USPTO, the Applicant respectfully requests that based on the Applicant's arguments presented herein that the rejections for all claims be withdrawn and all active claims now be allowed.

If the Examiner believes a telephone conference would be useful to advance the prosecution of this application, the Applicant can be reached any time at (304)290-9942.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Gary J. Morris", is written over a horizontal line.

Gary J. Morris  
Applicant  
Reg. No. 56,689